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Proposed Registration Decision PRD2013-17

Corn Gluten Meal

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

Proposed Registration Decision for Corn Gluten Meal

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal, containing the technical grade active ingredient corn gluten meal, which is intended for pre-emergent inhibition of weed seed germination in flower, vegetable, and fruit gardens.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on corn gluten meal, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on corn gluten meal, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Corn Gluten Meal?

Corn gluten meal is the active ingredient of Wilson Garden Weeder with Corn Gluten Meal, which is intended for pre-emergent inhibition of weed seed germination in flower, vegetable, and fruit gardens. Wilson Garden Weeder with Corn Gluten Meal is for domestic use only.

The mode of action of corn gluten meal is to prevent normal development of plant roots by releasing organic dipeptides into soil and inhibiting root formation of germinating seeds. Corn gluten meal does not prevent seed germination or affect root systems of established plants but rather causes seedlings with less than normal root systems to succumb to dehydration when exposed to drought stress.

Health Considerations

Can Approved Uses of Corn Gluten Meal Affect Human Health?

Corn gluten meal is unlikely to affect human health when used according to label directions.

Exposure to corn gluten meal may occur when applying the end-use product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient corn gluten meal is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. Therefore, precautionary statements alerting users to the eye irritation and sensitization potential of corn gluten meal are required on the labels for Corn Gluten Technical and the end-use product Wilson Garden Weeder with Corn Gluten Meal.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the information available on corn gluten meal, exposure to humans from domestic use of Wilson Garden Weeder with Corn Gluten Meal is not expected to be of concern due to the low toxicity of corn gluten meal and precautionary statements present on the end-use product label that are aimed at mitigating exposure.

Residues in Food and Water

Dietary risks from corn gluten meal on food and water are not of concern.

Wilson Garden Weeder with Corn Gluten Meal is proposed for use on domestic vegetable, fruit, and ornamental gardens as a pre-emergent herbicide to inhibit seed growth, and the proposed use is not expected to raise any dietary concern.

No risk due to exposure from drinking water is anticipated as corn gluten meal, by its organic nature, is expected to be degraded in the environment.

Risks From Handling Corn Gluten Meal

Risks are not of concern when corn gluten meal is used according to label directions, which include precautionary statements.

Wilson Garden Weeder with Corn Gluten Meal is to be applied directly from the packaged container. Residential exposure to individuals applying the end-use product is not expected to result in unacceptable risk when the product is used according to label directions. Precautionary statements on the label of the end-use product are considered adequate to protect individuals from residential exposure.

Since the end-use product is granular in form and is to be applied directly from the packaged container, bystander exposure is expected to be negligible.

Precautionary statements on the label of Wilson Garden Weeder with Corn Gluten Meal are considered adequate to protect individuals, children and pets from domestic use of this product.

Environmental Considerations

What Happens When Corn Gluten Meal Is Introduced Into the Environment?

Corn gluten meal is not expected to pose significant environmental risk when used under the proposed use pattern.

Corn gluten meal is derived from a naturally-occurring substance and is not expected to be persistent in the environment. It has a non-toxic mode of action and a long history of use as an animal food commodity, fertilizer and more recently as a pre-emergent herbicide in turf. Given the limited exposure expected from residential garden use, the risk to non-target organisms from corn gluten meal in the end-use product, Wilson Garden Weeder with Corn Gluten Meal is expected to be negligible.

Value Considerations

What Is the Value of Wilson Garden Weeder with Corn Gluten Meal?

Wilson Garden Weeder with Corn Gluten Meal, as a pre-emergent treatment in flower, vegetable, and fruit gardens, provides inhibition of weed seed germination

A pre-emergent application of Wilson Garden Weeder with Corn Gluten Meal at the 300 g per m^2 rate provides inhibition of weed seed germination, including annual bluegrass, black medic, black nightshade, buckhorn plantain, catchweed bedstraw, lamb's-quarters, creeping bentgrass, curly dock, dandelion, giant foxtail, large crabgrass, orchard grass, purslane, white clover, redroot pigweed, and smooth crabgrass in flower, vegetable, and fruit gardens.

There are a few non-conventional herbicides for weed management in domestic flower, vegetable, and fruit gardens. The expansion of corn gluten meal for use in gardens may provide a useful tool for pre-emergent weed management to home gardeners.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the technical and end-use product labels to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The signal words "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT" are present on the principal display panels of the labels of Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal.

Both the technical and end-use product labels have precautionary statements, such as "Avoid contact with skin, eyes or clothing," "May cause sensitization," and "Avoid breathing/inhaling dusts."

The end-use product label also instructs users not to apply the product if a member of the household has a sensitivity or allergy to corn, and not to apply under windy conditions.

The following additional statement: "Keep pets away from treated areas until the applied product is no longer visible" is also required on the end-use product label.

Next Steps

Before making a final registration decision on corn gluten meal, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on corn gluten meal (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Corn Gluten Meal

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Corn gluten meal
Function	Herbicide
Chemical name	
1. **International Union of Pure and Applied Chemistry (IUPAC)**	Not applicable
2. **Chemical Abstracts Service (CAS)**	Not applicable
CAS number	66071-96-3
Molecular formula	Not applicable
Molecular weight	Not applicable
Structural formula	Not applicable
Purity of the active ingredient	100%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Corn Gluten Technical

Property	Result
Colour and physical state	Gray to yellow granules
Odour	Odourless
Melting range	N/A
Boiling point or range	N/A
Density	0.6–0.8 g/cm^3
Vapour pressure at 20°C	N/A
Henry's law constant at 20°C	N/A
Ultraviolet (UV)-visible spectrum	N/A

Property	Result
Solubility in water	10%
Solubility in organic solvents at 20°C (g/100 mL)	N/A
n-Octanol-water partition coefficient (K_{OW})	N/A
Dissociation constant (pK_a)	N/A
Stability (temperature, metal)	Stable at room temperature. Decomposes at 95°C.

End-Use Product—Wilson Garden Weeder with Corn Gluten Meal

Property	Result
Colour	Gray to yellow
Odour	Odourless
Physical state	Solid
Formulation type	Granular
Guarantee	100%
Container material and description	Plastic jug with shaker dispenser lid, 0.5–25 kg
Density	0.5–0.6 g/cm^3
pH of 1% dispersion in water	N/A
Oxidizing or reducing action	N/A
Storage stability	Expected to be stable
Corrosion characteristics	Not corrosive
Explodability	Not expected to be explosive

1.3 Directions for Use

Wilson Garden Weeder with Corn Gluten Meal is a non-selective pre-emergent herbicide for inhibition of weed seed germination in flower, vegetable, and fruit gardens (domestic uses only) (Table 1.3.1). Wilson Garden Weeder with Corn Gluten Meal may be applied at the rate of 300 g per m^2 as per label directions only. Wilson Garden Weeder with Corn Gluten Meal does not affect established weeds.

Table 1.3.1 Weed claims for Wilson Garden Weeder with Corn Gluten Meal at the rate of 300 g per m^2

Grasses	Broadleaf Weeds
Inhibition of seed germination of annual bluegrass, creeping bentgrass, giant foxtail, large crabgrass, orchard grass, and smooth crabgrass.	Inhibition of seed germination of black medic, black nightshade, buckhorn plantain, catchweed bedstraw, lamb's-quarters, curly dock, dandelion, purslane, white clover, and redroot pigweed

The label also includes a number of cautionary statements relating to the conditions of application:

- Do not apply the product directly on seeded areas as it may inhibit seeds from germination.
- Apply when soil is moist or when rain is forecasted within 2 days.
- When seeding new gardens, plant seeds in rows and apply this product in between rows.
- Excessive moisture at time of treatment may reduce the effectiveness of the product.
- Reapply every 4–6 weeks depending on the density (bare soil exposure) of the garden.

1.4 Mode of Action

The mode of action of corn gluten meal is to prevent normal development of roots by releasing organic dipeptides into soil and inhibiting root formation of germinating seeds. Corn gluten meal does not prevent seed germination or affect the root systems of mature plants but rather causes seedlings with less than normal root systems to succumb to dehydration when exposed to drought stress.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the protein and water content in Corn Gluten Technical have been assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The enforcement analytical method is not required for this product.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

As the registration application concerns the addition of major new uses to the registered technical grade active ingredient corn gluten meal (Corn Gluten Technical, Registration Number 27726) and to repack it as a new end-use product for domestic use, no toxicological studies are required for Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal.

Based on the available information for corn gluten meal, both Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal are expected to be minimally toxic via the oral, dermal and pulmonary routes, minimally irritating to the skin, and mildly irritating to the eyes if both products conform to the mycotoxin guidelines established by the Canadian Food Inspection Agency (CFIA). Therefore, it is required that the mycotoxin levels present in the products do not exceed the tolerance levels established by the CFIA for feeds. In addition, they are expected to be potential sensitizers. There was no evidence to indicate that Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal are carcinogenic, genotoxic, neurotoxic, and/or a developmental/reproductive toxicant.

The most common adverse effect reported in humans for corn and corn by-products in the published literature is allergy. Symptoms include dermal reactions, respiratory ailments, gastrointestinal difficulties and severe anaphylaxis. Adverse effects were also reported for corn dusts. However, these effects are limited mainly to grain and feed workers who are exposed to these dusts in enclosed spaces on a daily basis. In addition, the cause of these reactions is still debated as corn and other grain dusts may contain numerous bacterial and fungal contaminants which can induce allergic and/or toxic reactions. Many of the fungi that grow on raw corn produce mycotoxins that may not be removed during wet-milling. Therefore, feed-grade corn gluten meal may also contain contaminating species of fungi particularly from the genus *Fusarium* and/or their associated mycotoxins, including fumonisins (B1, B2, B3), trichothecenes (types A and B), zearalenone, aflatoxin and ochratoxin A. The amount of these mycotoxins present in feed-grade corn gluten meal is regulated by the CFIA. Currently, aflatoxin is the only mycotoxin regulated in the *Feeds Act* and Regulations; however, recommended tolerance levels have been established for many of the remaining groups of mycotoxins.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management section of Health Canada's website at www.healthcanada.gc.ca/pmra. Incidents were searched and reviewed for the active ingredient corn gluten meal. As of 5 February 2013, there were four human and 28 domestic animal incident reports in the PMRA database involving the active ingredient corn gluten meal. Of these, all four human incidents had a high degree of association and 25 of the 28 domestic animal incidents were considered to have at least some degree of association with exposure to the pesticide.

Human incidents were minor or moderate in nature and were considered to be highly probably or probably related to exposure to corn gluten meal. In three of the incidents the subjects experienced skin or eye irritation following application of the product.

Since the proposed end-use product is dispensed directly from the container, and the user does not have to transfer the product from a bag to a spreader as in the incidents noted above, and the proposed label contains warnings to mitigate the type of reactions reported in the above noted incidents, the reported human incidents supported the current toxicity database for corn gluten meal; however, they did not impact the risk assessment for corn gluten meal.

Domestic animal incidents were classified as minor or moderate. Almost all cases were considered to be at least possibly related to ingestion of corn gluten meal, and one third of incidents had a high degree of association with ingestion of the product. Gastrointestinal effects such as vomiting and diarrhea were reported in almost all incidents.

The proposed product Wilson Garden Weeder with Corn Gluten Meal is formulated as a granular herbicide containing 100% corn gluten meal, similar to the product in the reported incidents, however, the application rate is higher and the application intervals are more frequent. Similar exposure scenarios as those noted in the animal incidents can be expected for Wilson Garden Weeder with Corn Gluten Meal. Therefore, an additional label statement is required on the end-use product label as a mitigation strategy to keep companion animals off the treated areas.

Other Incident Reports

No other incident reports were located in the California Department of Pesticide Regulation Pesticide Illness Query database or the USEPA database.

3.2 Food Residue Exposure Assessment

Corn gluten meal is used as feed for cattle, poultry, fish, and dogs. The corn gluten meal in the technical grade active ingredient is of low acute oral toxicity if it conforms to the mycotoxin guidelines established by the Canadian Food Inspection Agency (CFIA). Therefore, mycotoxin levels present in the technical and end-use products are required not to exceed the tolerance levels established by the CFIA for feeds. Corn gluten meal is not genotoxic, carcinogenic or considered to have any significant effect with respect to short-term or chronic toxicity, or reproductive toxicity. Since the granular end-use product is applied on top of the soil and is not likely to come in contact with foods such as fruits and vegetables, exposure from the diet is considered negligible. As such, a quantitative assessment of residues from dietary intake is unnecessary.

Moreover, corn gluten meal is designated by the United States Food and Drug Administration (USFDA) as Generally Recognized As Safe (GRAS). In the United States, the Environmental Protection Agency has exempted corn gluten meal from the requirement of a tolerance for residues when used as an herbicide in or on all food commodities when applied in accordance with good agricultural practice. There are no CODEX values for corn gluten meal.

Due to the low oral toxicity of corn gluten meal and the anticipated negligible residue of the end-use product from its proposed use on vegetable and fruit gardens, there is no dietary concern.

3.2.1 Drinking Water

Since the proposed application of Wilson Garden Weeder with Corn Gluten Meal is to the soil surface, and by its organic nature corn gluten meal is expected to be degraded in the environment, no risk due to exposure from drinking water is anticipated.

3.2.2 Maximum Residue Limits (MRLs)

A maximum residue limit (MRL) for corn gluten meal is not necessary because dietary exposure to corn gluten meal from the proposed use of the end-use product is considered negligible.

3.3 Residential Exposure and Risk Assessment

3.3.1 Use Description

The proposed end-use product is for domestic use as a pre-emergent herbicide in ornamental, vegetable, and fruit gardens (USC 14 and USC 27) for the inhibition of annual bluegrass, black medic, black nightshade, buckhorn plantain, catchweed bedstraw, lamb's-quarters, creeping bentgrass, curly dock, dandelion, giant foxtail, large crabgrass, orchard grass, purslane, white clover, redroot pigweed, and smooth crabgrass. The end-use product is granular and is to be applied directly from the packaged container (500 g or 2 kg in polyethylene containers) at an application rate of 300 grams/m^2 (1 L container treats 3 m^2). The label instructs application before weed emergence and to remove any existing weeds prior to application, with best timing for application being after the desired plants have established. The product is not to be applied on seeded areas. There is no loading or mixing equipment required for application. Reapplication is recommended every 4–6 weeks depending on the density of garden (bare soil exposure), and there is no proposed maximum number of applications. Light watering is recommended to the application site if no rain occurs within two days of the treatment.

3.3.2 Domestic Exposure and Risk Assessment

Residential exposure to Wilson Garden Weeder with Corn Gluten Meal is expected to be minimal from the proposed use. There is no loading or mixing required as the proposed end-use product is to be applied directly from the packaged container, which has a lid with a sliding cover from where the product will exit.

The end-use product is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. The proper use and handling of the proposed end-use product, following label directions, is not likely to result in repeated or prolonged human exposure by any routes at a concentration that is likely to raise toxicological concerns.

To protect people who are sensitive to corn, the end-use product label instructs domestic users to not apply Wilson Garden Weeder with Corn Gluten Meal if a member of the household has a sensitivity or allergy to corn. Also, the label instructs that application should not be done under windy conditions, and domestic users are required to avoid contact of the product with the skin, eyes or clothing, and avoid breathing dust.

3.3.3 Bystander Exposure

Since the end-use product is granular in form and is to be applied directly from packaged container, bystander exposure is expected to be negligible. Also, the label forbids product use during windy conditions, thereby limiting bystander exposure from possible wind drift.

3.3.4 Postapplication Exposure

As the proposed product is a pre-emergent herbicide for vegetable, fruit, and ornamental gardens, and the only postapplication activity expected is watering the treated surface if required, there is minimal postapplication exposure.

A number of domestic animal incident reports involving corn gluten meal have been received by the PMRA and almost all cases were considered to be at least possibly related to ingestion of corn gluten meal. Moreover, one third of incidents had a high degree of association with ingestion of the product. As the application rate is higher and the application intervals are more frequent for the end-use product, similar exposure scenarios as those noted in the animal incidents can be expected for Wilson Garden Weeder with Corn Gluten Meal. Therefore, an additional precautionary label statement is required on the end-use product label to prevent post-application exposure of companion animals to the end-use product.

Due to the relatively low toxicity of the end-use product, its granular form, method of application (dispersed from the container), and the precautionary statements present on the draft label, it is expected that residential exposure to domestic users and bystanders from the proposed use of the end-use product is not of concern.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Corn gluten meal is not expected to be persistent in the environment since it is insoluble in water and therefore not expected to leach in soils and, as a protein, expected to break down rapidly when applied to soil. The label for Wilson Garden Weeder with Corn Gluten Meal recommends that applications are lightly watered in unless rain is forecast within 2 days of treatment. This should further contribute to the break down of the granules.

4.2 Effects on Non-Target Species

Corn gluten meal is a feed-grade material and has historically been used in the manufacture of food for pets, farm animals and fish. It is also used as a pre-emergent herbicide and fertilizer in turf. It is not expected to adversely affect non-target terrestrial or aquatic organisms. Based on the current use pattern of Wilson Garden Weeder with Corn Gluten Meal, the exposure of non-target terrestrial and aquatic organisms to corn gluten meal is expected to be minimal. As a result, environmental risk to terrestrial and aquatic organisms is expected to be negligible.

4.2.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website. Incidents were searched and reviewed for the active ingredient corn gluten meal. As of 15 March 2013, there were 12 environmental incident reports in the PMRA database involving the active ingredient corn gluten meal. All incidents reported that the product was applied to residential lawns, and the reported injury was to the lawn. Symptoms reported were considered minor and included 'abnormal leaf discolouration', 'death', and 'visible injury'.

5.0 Value

5.1 Effectiveness Against Pests

Value information submitted for review included scientific rationales and efficacy studies from a total of 16 published scientific papers, research briefings, and abstracts. Studies included in these documents were conducted in greenhouses or fields in Iowa, California, West Virginia, and Oklahoma during a nine-year period. Efficacy of a pre-emergent application of Wilson Garden Weeder with Corn Gluten Meal at various rates (ranging from 5.5 to 973 g per m^2) was evaluated for all labelled weeds. The herbicide treatments were applied pre-emergence to target weeds and reduction in weed survival was reported compared to an untreated control.

In addition to the submitted information, corn gluten meal as a pre-emergent herbicide has been registered for inhibition of seed germination of dandelion, large and smooth crabgrass, and white clover in turf grass since 2003.

5.1.1 Acceptable Efficacy Claims for Wilson Garden Weeder with Corn Gluten Meal

Adequate information was provided to support efficacy claims for Wilson Garden Weeder with Corn Gluten Meal applied at the rate of 300 g per m^2 (Table 5.1.1.1).

Table 5.1.1.1 Weed claims for Wilson Garden Weeder with Corn Gluten Meal at the rate of 300 g per m^2

Grasses	Broadleaf Weeds
Inhibition of seed germination of annual bluegrass, creeping bentgrass, giant foxtail, large crabgrass, orchard grass, and smooth crabgrass.	Inhibition of seed germination of black medic, black nightshade, buckhorn plantain, catchweed bedstraw, lamb's-quarters, curly dock, dandelion, purslane, white clover, and redroot pigweed

5.2 Phytotoxicity to Host Plants

Phytotoxicity to host plants is not of concern for the following reasons:

- Corn gluten meal inhibits seed germination but not established plants.
- The following cautionary statements are included on the label.
  - Do not apply the product directly on seeded areas as it may inhibit seeds from germinating.
  - When seeding new gardens, plant seeds in rows and apply this product in between rows.

5.3 Impact on succeeding Crops

According to the product label and information from the submitted studies, inhibitory effects of corn gluten meal last only five weeks. Therefore, impact on succeeding crops is not of concern.

5.4 Economics

No market analysis was assessed for this product. There are a few non-conventional herbicides for weed management in domestic flower, vegetable, and fruit gardens. The expansion of corn gluten meal from use on turf grass to gardens may provide a useful tool for pre-emergent weed management to home gardeners.

5.5 Sustainability

5.5.1 Survey of Alternatives

There are a few non-conventional herbicides available for weed management in domestic gardens. Such products include acetic acid and ammonium soap of fatty acids, which are registered as post-emergent treatments. As post-emergent herbicides, application of acetic acid and ammonium soap of fatty acid may be hard to avoid contact with desirable garden plants.

In areas where a suitable herbicide is not available for home gardens, weed management options are commonly limited to hand weeding or mulch covers. Hand weeding can be physically demanding and mulch covers, especially plastic, can be an environmental concern.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Pre-emergent application of Wilson Garden Weeder with Corn Gluten Meal does not restrict sequential uses of other pesticides with alternate modes of action if it is permitted, for example, post-emergent applications of acetic acid and ammonium soap of fatty acids.

Corn gluten meal, a by-product of wet-milling process of corn, could be used as a component of a sustainable integrated pest management program in home gardens.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, corn gluten meal and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

> Corn gluten meal does not meet the Track 1 criteria and will not form any transformation products which meet the Track 1 criteria. Corn gluten meal is a naturally occurring substance and is not expected to be persistent in the environment.

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

> Technical grade corn gluten meal and the end-use product Wilson Garden Weeder with Corn Gluten do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.
>
> The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02[9].

7.0 Summary

7.1 Human Health and Safety

Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal are expected to be minimally toxic via the oral, dermal and pulmonary routes, minimally irritating to the skin, and mildly irritating to the eyes if both products conform to the mycotoxin guidelines established by the Canadian Food Inspection Agency (CFIA). Therefore, it is required that the mycotoxin levels present in the products do not exceed the tolerance levels established by the CFIA for feeds. The proposed technical grade active ingredient and the end-use product are expected to be potential sensitizers. There was no evidence to indicate that Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal are carcinogenic, genotoxic or teratogenic.

When used as proposed, dietary exposure to corn gluten meal is expected to be negligible and therefore, not expected to raise any toxicological concerns. As such, promulgation of maximum residue limits for corn gluten meal is not necessary.

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6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

9 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

Due to the relatively low toxicity of the end-use product, its granular form, method of application (dispersed from the container), and the precautionary statements present on the end-use product label, it is expected that residential exposure to domestic users and bystanders from the proposed use of the end-use product is not of concern. Precautionary statements are required on the end-use product label to prevent postapplication exposure of companion animals to corn gluten meal.

7.2 Environmental Risk

Corn gluten meal is not expected to be persistent in the environment. It has a non-toxic mode of action and a long history of use as an animal food commodity, fertilizer and more recently as a pre-emergent herbicide in turf. Given the limited exposure expected from residential garden use, the risk to non-target organisms from corn gluten meal in the end-use product, Wilson Garden Weeder with Corn Gluten Meal is expected to be negligible.

7.3 Value

The value information submitted to support the registration of Wilson Garden Weeder with Corn Gluten Meal is adequate to describe the efficacy claims in flower, vegetable, and fruit gardens. A single pre-emergent application of Wilson Garden Weeder with Corn Gluten Meal at the rate of 300 g per m^2 can be expected to result in the inhibition of seed germination of annual bluegrass, black medic, black nightshade, buckhorn plantain, catchweed bedstraw, lamb's-quarters, creeping bentgrass, curly dock, dandelion, giant foxtail, large crabgrass, orchard grass, purslane, white clover, redroot pigweed, and smooth crabgrass. For longer term weed management, repeat applications of Wilson Garden Weeder with Corn Gluten Meal every 4 to 6 weeks may be necessary.

The registration of Wilson Garden Weeder with Corn Gluten Meal may provide a useful tool for pre-emergent weed management to home gardeners since there are a very few non-conventional alternative herbicides available for domestic gardens. As a by-product of wet-milling process of corn, corn gluten meal could be used as a component of a sustainable integrated pest management program in home gardens.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Corn Gluten Technical and Wilson Garden Weeder with Corn Gluten Meal, containing the technical grade active ingredient corn gluten meal, for pre-emergent inhibition of weed seed germination in flower, vegetable, and fruit gardens.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

CAS	Chemical Abstracts Service
CFIA	Canadian Food Inspection Agency
cm	centimetres
DACO	data code
FDA	Food and Drug Administration
g	gram
GRAS	Generally Recognized As Safe
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
m	metre
mL	millilitre
MRL	maximum residue limit
N/A	not applicable
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy
US	United States
USC	Use Site Category
USEPA	United States Environmental Protection Agency
UV	ultraviolet

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
	1.0 Chemistry
1781259	2003, Corn Gluten Technical, DACO: 2.11,2.12.2,2.13.1,2.13.3,2.2 CBI
	2.0 Human and Animal Health
2194840	US EPA Biopesticides Registration Action Document: Corn Gluten Meal, DACO: 12.5.10,12.5.2,12.5.4,12.5.5,12.5.8
2217792	Wilson Garden Weeder, Use Description / Exposure Scenarios, DACO: 5.2, CBI
2194808	Waiver rationale for DACO 6 Metabolism, DACO: 0.17,6.3
	3.0 Environment
2194809	Waiver rationale for DACO 8.2.3.4.4 Anaerobic Soil, DACO: 0.17,8.2.3.5.4
2194810	Waiver rationale for DACO 9.6.3.1 and 9.6.3.2, DACO: 0.17,9.6.3.1,9.6.3.2
2194838	Dietary Interactions Between Lysine and Threonine in Broilers, DACO: 10.7.2,9.6.3.1,9.6.3.2
2194839	Comparison of Amino Acid Digestibility Determined Prececally or Based on Total Excretion of Cecectomized Laying Hens, DACO: 10.7.2,9.6.3.1,9.6.3.2
2194840	US EPA Biopesticides Registration Action Document: Corn Gluten Meal, DACO: 12.5.10,12.5.2,12.5.4,12.5.5,12.5.8
2289779	2011, Energy determination of corn co-products fed to broiler chicks from 15 to 24 days of age, and use of composition analysis to predict nitrogen-corrected apparent metabolizable energy, 2011 Poultry Science 90 :1999-2007, DACO: 10.7.2
	4.0 Value
2194816	2012, Weed Control: Case studies in flowers and strawberries, DACO: 10.1,10.2.3.1
2194817	2010, Influence of corn gluten meal on squash plant survival and yield, DACO: 10.1,10.2.1,10.2.3.1,10.2.3.4(B),10.3.2
2194818	Organic Weed Control Solutions in Broccoli, DACO: 10.1,10.2.3.3(B)
2194819	1995, Greenhouse Screening of Corn Gluten Meal as a Natural Control Product for Broadleaf and Grass Weeds, DACO: 10.2.3.3(B)
2194820	2005, Evaluation of Weed Control Practices in an Organic Bell Pepper Production System, DACO: 10.2.3.3(B)
2194825	2005, Corn gluten meal: Alternative weed control for squash, DACO: 10.2.3.3(B)

2194826 Weed control with hydrophobic and hydrous kaolin clay particle mulches, DACO: 10.2.3.3(B)
2194827 2006, Non-pungent jalapeno peppers: Corn gluten meal as an organic herbicide, DACO: 10.2.3.3(B)
2194828 2006, Corn gluten meal as a herbicide in non-pungent jalapeno peppers, DACO: 10.2.3.3(B)
2194830 2006, Corn gluten meal and spring-transplanted onions (Allium cepa L.): crop safety, weed control, and yields, DACO: 10.2.3.3(B)
2194831 2007, Corn Gluten Meal as an Alternative Weed Control Option for Spring-Transplanted Onions, DACO: 10.2.3.3(B)
2194832 1993, The Use of Corn Gluten Meal as a Natural preemergence Weed Control in Turf, DACO: 10.2.3.3(B)
2194833 1993, Evaluation of Corn Gluten Meal as a Natural, Weed Control Product in Strawberry, DACO: 10.2.3.3(B)
2194834 2000, Corn gluten meal - a natural preemergence herbicide: Effect on vegetable seedling survival and weed cover, DACO: 10.2.3.3(B)
2194835 2005, Investigation in Organic Weed Control Methods, DACO: 10.2.3.3(B)
2194836 1997, Inhibitory Activity of Corn Gluten Hydrolysate on Monocotyledonous and Dicotyledonous Species, DACO: 10.1,10.2.1,10.2.2,10.2.3.3(B)

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

Regulatory Note REG2003-09 – *Corn Gluten Meal*

ii) Unpublished Information

1.0 Environment

2290192 2013, Summary Evaluation Report for Environmental Incident Reports